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REMARKS

Claims 1-9 are pending; claims 1-9 are under non-final rejection.

The examiner has rejected claims 1 and 5 under 35 U.S.C. § 102, in view of Hansson et al. (US 5,656,605).

The present invention is to an artificial tube for nerve which comprises fine fibrous collagen bodies in the lumen of a tube, which is comprised of a biodegradable and absorbable material. The voids inside the fine fibrous collagen bodies are filled with laminin.

Hansson discloses a polyglycolic acid artificial tube that has a matrix-forming material containing collagen, nerve-growth stimulating agents and growth factors. However in Hansson, the invention has "guiding filaments" as a required element of the invention. See Hansson et al., Column 2, lines 41-52 and column 4, lines 8-14. The collagen of claims 1 and 5 of the instant application do not use guide filaments as disclosed by Hansson. The collagen and guide filaments of Hansson are not the fine fibrous collagen that is used in the instant application.

The fine fibrous collagen that is used in this invention is quite different from that used in Hansson. The fine fibrous collagen of the present application has a unique network structure. Figures 2-4 show the unique fibrous structure that is present in the collagen of this invention. The fine fibrous collagen of the instant application has a network structure which consists of voids which are scattered throughout the surface and bodies of the collagen. Hansson nowhere discloses a collagen with this structure.

The fine fibrous collagen of this invention is peferably made by a particular method, e.g. the method of claims 6-9. This method includes the steps of freezing a collagen hydrochloric acid solution layer and a subsequent step of freeze drying. See page 11, lines

20-36 of the instant specification. Hansson does not disclose the use of a fine fibrous collagen made by this method.

Thus, because Hansson does not disclose the use of a fine fibrous collagen as defined in the instant application, it is respectfully submitted that Hansson does not anticipate the instant invention under 35 U.S.C. § 102.

The examiner has rejected claims 2-4 under 35 U.S.C. § 103(a) over the aforementioned Hansson in view of Buscemi et al. (US 5,769,883).

Buscemi does not disclose the elements of the instant invention. Buscemi does not disclose a fine fibrous collagen or the method of preparation of collagen in the instant application.

In Buscemi a collagen IV is used that has a completely different higher order structure than the collagen I or III that is used in the instant invention. The fine fibrous collagen of the instant application has a periodic filament structure, whereas the collagen IV of Buscemi does not form a filament structure, but forms a non-fibrous network structure. Buscemi also fails to disclose the preparation method of the fine fibrous collagen that is used to prepare the collagen of the instant application, and illustrated in the figures.

In Buscemi the invention is stated to include collagen and laminin. However, the laminin binds to the collagen in Buscemi through binding sites that are present in the collagen IV. The combination of collagen and laminin in Buscemi results in the formation of a relatively small network structure of laminin that is formed inside of a relatively large network structure of collagen IV. This is a structure that is completely different from the fine fibrous collagen that is disclosed in the instant application.

Therefore, the combination of references cited by the examiner fails to disclose all of the elements of the claimed invention as required by 35 U.S.C. § 103.

Also the invention disclosed by Buscemi is to a drug delivery system and is not used for nerve re-generation. There is nowhere a suggestion or motivation to combine the Hansson and Buscemi references. There is nothing in the references themselves, in some other prior art, or in any specific knowledge that is generally available to one skilled in the art, that suggests combining these references. Thus, it is respectfully submitted that the Buscemi and Hansson references cannot properly be combined under 35 U.S.C. § 103 to render the instant invention unpatentable.

Claims 6-9 have been rejected under 35 U.S.C. § 103(a) over the aforementioned Hansson in view of Silver et al. (US 4,703,108). Silver discloses a method of preparing biodegradable collagen based matrices.

The combination of Silver and Hansson does not disclose all of the elements of the invention in the instant application as required by 35 U.S.C. § 103.

The Silver collagen matrices are prepared by using a crosslinking agent such as a carbodiimide (column 3, lines 39-50). These crosslinking agents use the carboxyl and/or the amide groups of the collagen molecules to form the chemical crosslinks. However cells in the body would need to use these same carboxyl and/or amide sites for anchoring themselves when the artificial nerve tube is implanted into the body. Thus, the adhesion properties of such a system would be lowered. In claims 6-9 of the instant application a thermal crosslinking treatment is used and no crosslinking agent is introduced.

Again there is no suggestion or motivation to combine the Hansson and Silver references. There must be something specific in the references themselves, in some other prior art, or in some specific knowledge that is generally available to one skilled in the art to properly combine references. Thus, it is respectfully submitted that the Silver and Hansson references can not properly be combined under 35 U.S.C. § 103 to render the instant invention unpatentable.

The examiner has rejected claims 1-4 under the judicially created doctrine of obviousness type double patenting over US 6,090,117.

Applicants respectfully submit that the invention of claims 1-4 of the instant application are patentably distinct from claims 1,4,5, and 6 of US 6.090,117 and that a terminal disclaimer is not required.

In the invention of the instant application, laminin is present in the voids inside of the fine fibrous collagen, which is not the case in the invention of claim 1 of US 6,090,117.

The cavities in US 6,090,117 pass through the biodegradable and absorbable material in the tube substantially in the direction of the axis of the nerve tube. The artificial tube for nerve in the instant application does not have such cavities going through the fine fibrous collagen bodies, it has voids which are scattered all over the surface and inside of the fine fibrous collagen bodies.

Further, the artificial tube for nerve of the present invention succeeded in recovering 80 mm of a gap in the nerve (page 16, line 36 to page 18, line 1) which is greater than the 25 mm gap that was recovered in the cited patent. (See US 6,090,117 Column 11, lines 50-63)

Therefore these inventions are patentably distinct and applicant here suggests that no terminal disclaimer is needed.

It is respectfully submitted that the present application is in condition for allowance. An early consideration and notice of allowance are earnestly solicited.

Respectfully submitted,

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